

Clinical Alert

May 2015

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Department of Health
and Mental Hygiene**

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The Rights of Psychiatric Patients and Intramuscular Medications

Recent hospital surveys for the Center for Medicaid and Medicare Services (CMS) Condition of Participation (COP) for patient rights have uncovered a disturbing trend wherein physicians are writing orders for routine psychiatric medications to be given as either per mouth (PO) or via intramuscular injection (IM) in the event of patient refusal of PO medications. This practice circumvents the patient's right to refuse medication, may be physically and emotionally traumatic for the patient and staff, and is a deficient practice according to both the COP for patient rights (42 CFR 482.13(e)) and the Maryland Health-General Article §10-708.

While the routine, or even PRN (as needed) use of psychiatric or psychotropic medications specific to the patient's diagnosis and condition, at standard doses, does not constitute chemical restraint,¹ writing an order that the medications should be given PO "or IM if patient refuses" makes the administration of that medication a chemical restraint. Adding that additional part of the order violates several of the standards under the patient rights COP. All patients, including voluntary and involuntarily admitted psychiatric patients, have the right to refuse medications and treatments. It is the route (IM) and the reason (patient refusal of PO) that makes medications administered in this manner chemical restraints. Ordering the medication to be given IM if the patient refuses changes the order to a de facto PRN chemical restraint. In addition, giving someone an injection after he or she has refused oral medications will most likely necessitate physically restricting the patient's movements against his or her will. This physical hold is also a restraint and is subject to the requirements of the COP, including getting a physician order prior to holding the patient and performing a face-to-face examination within one hour.

Medication may be given without the patient's consent only under the following conditions:

1. The patient is having a behavioral emergency and is exhibiting behaviors that are immediately dangerous to the patient or others. The documentation must specifically describe the behaviors and the less restrictive interventions considered or attempted prior to forced medication administration. This type of medication administration requires the hospital to meet the requirements of the standards for restraint use, including getting a physician order for each incident, and performing a face-to-face examination within one hour of administration.
2. Medications may be given with the approval of a guardian or personal representative who has the legal authority to make health care decisions for the patient. For adults, the hospital would have to go through the process of certifying incapacity unless there is an advance directive in effect in which a patient has already ceded decision-making authority to a health care agent. Psychiatric patients may have a psychiatric treatment-specific advance directive detailing their wishes regarding medications and care in the event they are incapacitated by their mental illness.
3. Medications may be given against a patient's will under a court order or at the direction of a clinical review panel.² In Maryland, the clinical review panel consists of members of the hospital's medical staff and the chief executive officer or designee along with a non-physician mental health professional. The panel is charged with reviewing the patient's clinical record, hearing from the treating physician, the patient, and others, and rendering a decision regarding whether the benefits of forced medications outweigh the risks. While the treating physician may give his or her opinion to the panel, the physician does not get a vote on whether to force medications. The patient may also speak to the panel

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giving his or her reasons for refusing the medication, and may confer with a lay advisor and present witnesses to the panel. Each medication recommended by the treating physician and refused by the patient must undergo this review. Once the decision has been made by the clinical review panel, the patient has 48 hours to file an appeal with an administrative law judge, who then has seven days to hold a hearing. This review process must be repeated every 90 days.

Please note: The Health-General Article referenced above applies only to distinct psychiatric hospitals and acute general hospitals with inpatient psychiatric units.³ The need for a clinical review panel does not apply to acute general hospitals that do not offer inpatient psychiatric services. In those hospitals, the only acceptable reasons for forced medications is a behavioral emergency, or in an incompetent patient, with the consent of an authorized decision maker.

When physicians write orders for medications without specifying one route only, the nurse administering the medications is left with the decision as to how to give the medication. The injections are given only when the patient refuses to take the medications orally. Besides violating the patient's right to refuse medications, this action means that the physician is not consulted prior to the use of a restraint as called for in regulation.

Physicians at one hospital were noted to have routinely ordered chlorpromazine (Thorazine), one of the first antipsychotics, "IM PRN for agitation." Chlorpromazine was not a standard medication for the patients reviewed, and was only ordered to be used as needed during "agitation." The term agitation is imprecise and highly subjective, making the threshold for administering chlorpromazine variable among the nurses. This variability, along with the lack of a physician consult, is precisely why chemical restraints are not allowed to be used PRN and why the use of any chemical restraint

requires adherence to the COPs for restraint use and, if applicable, the Health-General Article §10-708.

In addition to the regulatory hazards to the hospital, chemical restraints are not without risk to the patient, and staff may be harmed while attempting to restrain the patient in order to give the injection. While no reports of serious events specific to chemical restraints have been submitted under the Maryland Patient Safety Program, we have received several reports of serious patient injuries that have occurred while staff were trying to restrain an agitated and combative patient. For instance, one patient suffered a paralyzing neck injury while being wrestled onto his bed prior to being given emergency medications. There have also been reports of broken bones and fatal or near-fatal asphyxia injuries acquired during restraint episodes. Any time that staff do not have to lay hands on patients, whether it is to control behavior or to administer IM medications, patients and staff are safer.

Hospital surveyors from the Office of Health Care Quality find no class of medications, other than psychiatric medications, ordered with an alternate route to be used in the event of patient refusal. If this method of ordering medications is not the standard of care for all other classes of medications, it should not be permissible under hospital policy for psychiatric medications. Nothing in this Clinical Alert should be construed as a ban on chemical restraints as an emergency response to dangerous behavior. But, if used, the requirements of the patient rights COPs for hospitals and Maryland law must be followed.

References:

¹ 42 CFR 482.13(e)(1)(i)(B)

² Maryland Health General Article §10-708

³ Maryland Health General Article §10-701